

Notice of Allowability

Application No.

09/988,109

Examiner

Humera N. Sheikh

Applicant(s)

AUWETER ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06 December 2005.
2. ☒ The allowed claim(s) is/are 1-6,9-16,28-33 and 43.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 12/06/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Preliminary Submission and Amendment and Applicant's Arguments/Remarks, all filed 09/06/05 and the Supplemental Preliminary Submission and Amendment, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 12/06/05 is acknowledged.

Claims 1-6, 9-16, 28-33 and 43 are pending in this action. Claims 1, 5, 11 and 28 have been amended. New claim 43 has been added. Claims 1-6, 9-16, 28-33 and 43 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/06/05 has been entered.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 1, line 4, after the title of the invention, the phrase **“This application claims foreign priority to German Application No. 10059213.9 filed November 29, 2000 and German Application No. 10129713.0 filed June 22, 2001”** has been added.

In the Abstract:

The heading of the Abstract entitled ‘Substitute Abstract’ has been changed to **“Abstract”**.

Allowable Subject Matter

Claims 1-6, 9-16, 28-33 and 43 are allowed.

The following is an examiner’s statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Horn *et al.* – U.S. Patent No. 4,522,743) does not disclose nor fairly suggest or teach the instant process for producing solid preparations of at least one water-soluble, sparingly water-soluble or water-insoluble active compound comprising the step of the combined flocculation of the active ingredient and the protective colloid out of the dispersion. Applicant’s claims require the essential process step of flocculating the protective colloid out of the dispersion, together with the active compound, which is not disclosed or taught by the prior art. In stark contrast, Horn *et al.* teach increasing the active ingredient concentration in the dispersion, when a mixture of gelatin and gum arabic is

Art Unit: 1615

employed in the colloid, by forming a sedimentable coacervate of the gelatin and the gum arabic through a pH control. In this context, Horn *et al.* specifically point out that the finely divided carotenoids remain in the liquid phase when the sedimentable coacervate of the gelatin and gum arabic is formed. Thus, the formation of the coacervate, according to Horn *et al.*, serves to reduce the amount of colloid, which is present in the liquid phase, while, at the same time, maintaining the active ingredient in the liquid phase. The process and procedure employed by Horn *et al.* is the opposite of Applicant's invention, which requires that the proteinaceous protective colloid be flocculated out of the dispersion together with the active compound. The prior art fails to provide any motivation to employ a process for producing solid preparations comprising the step of combined flocculation of the protective colloid and active compound out of the dispersion as is instantly claimed. The prior art further fails to disclose such a process as instantly claimed whereby the pH of the dispersion is set to a value in the range of 4.0 to 5.5, as claimed in the present invention.

Hence, in view of the lack of teachings of the prior art, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

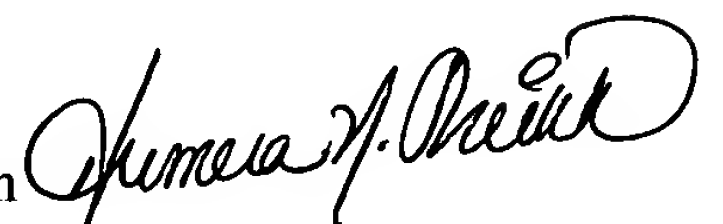
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

February 20, 2006


TC-1600

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